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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,353	02/26/2004	Arthur M. Krieg	C1039.70083US07	9688

7590 03/28/2007  
Helen C. Lockhart, Ph.D.  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, MA 02210

EXAMINER
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ARCHIE, NINA

ART UNIT	PAPER NUMBER
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1645

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/28/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/789,353

Applicant(s)

KRIEG ET AL.

Examiner

Nina A. Archie

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 28-36 is/are pending in the application.
- 4a) Of the above claim(s) 30 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-29, 31-33, 35 and 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/26/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Priority***

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

### ***Information Disclosure Statement***

The information disclosure statement filed on 2/26/2004 has been considered.  
An initialed copy is enclosed.

### ***Election/Restrictions***

Applicant's election without traverse of Group I claims 28-36 are acknowledged.

Claims 30 and 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply timely filed on 1/19/2007.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28 and 36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 101, 107-109, 120-122, 124 of copending Application No. 10/314,578.

In the instant case, the claims are drawn to an oligonucleotide, comprising: 5'-TGACGTT-3', 8-40 nucleotides in length, and having at least one phosphate backbone modification.

U.S. Application No. 10/314,578 claims (101, 107-109, 120-122, 124) teaches a an oligonucleotide, comprising: 5'-TGACGTT-3' (SEQ ID NO:343), 8-40 nucleotides in length, and having at least one phosphate backbone modification; a composition comprising the oligonucleotide of claim 28 and a pharmaceutically acceptable carrier.

Although the conflicting claims are not identical, they are not patentably distinct. The U.S. Application No. 10/314,578 recites the "an oligonucleotide". The composition anticipates the claims of the present application.

Thus, claims 28 and 36 encompassing the oligonucleotide in the present application are obvious over claims 101, 107-109, 120-122, 124 of U.S. Application No. 10/314,578.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 28 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyazaki et al 1993 Journal of Clinical Microbiology No. 8, Vol. 31 No. 8 pgs. 2228-2232 in view of Goodchild et al 1990 The American Chemical Society, Vol. 1, No. 3 pgs. 165-182.

Claims 28 and 35 are drawn to an oligonucleotide, comprising: 5'-TGACGTT-3', 8-40 nucleotides in length, and having at least one phosphate backbone modification.

Miyazaki et al teach an oligonucleotide, comprising: 5'-TGACGTT-3', 8-40 nucleotides in length (18-base).

Miyazaki et al does not teach an oligonucleotide having at least one phosphate backbone modification, wherein the phosphate backbone modification is a phosphorothioate.

Goodchild et al teaches an oligonucleotide wherein the phosphate backbone modification is a phosphorothioate (see pg. 167 column 1 last paragraph, column 2 last paragraph). Goodchild et al teaches that backbone modifications are utilized to improve the stability of the DNA to enzymatic degradation (see pg. 167 "Synthesis of Modified

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Oligonucleotides", pg. 175 "The Effect of Modification on Nuclease Resistance"). Goodchild et al. teaches that shorter oligonucleotides are taken up more rapidly (see pg. 176 column 1 paragraph 5).

It would have been prima facie obvious at the time the invention was made to modify the backbone of the oligonucleotide of Miyazaki et al to include phosphorothioate taught by Goodchild et al because Goodchild et al teaches that the backbone modifications prevent degradation by nucleases and increase or improve uptake (see section B pg. 167).

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miyazaki et al 1993 Journal of Clinical Microbiology No. 8, Vol. 31 No. 8 pgs. 2228-2232 and Goodchild et al 1990 The American Chemical Society, Vol. 1, No. 3 pgs. 165-182 as applied to claim 28 above, and further in view of Longiaru et al. Aug 3, 1993 US Patent No. 5,232,829.

Claim 36 are drawn to an oligonucleotide, comprising: 5'-TGACGTT-3', 8-40 nucleotides in length, and having at least one phosphate backbone modification.

The combination of Miyazaki et al and Goodchild et al is set forth above. The combination differs by not teaching a composition comprising the oligonucleotide of claim 28 and a pharmaceutically acceptable carrier.

Longiaru et al teaches a composition comprising an oligonucleotide (capture probe) and a pharmaceutically acceptable carrier (water). Longiaru et al teaches that the oligonucleotide is synthesized by phosphoramidite chemistry and thus the backbone has been modified (see column 7 lines.

It would have been prima facie obvious at the time the invention was made to modify the oligonucleotide of Miyazaki et al and Goodchild et al as combined supra by inclusion of the oligonucleotide in a pharmaceutically acceptable carrier taught by Longiaru et al. It would also have obvious because Longiaru et al and Miyazaki et al both use oligonucleotides for PCR amplification.

***Status of the Claims***

No claims allowed.

Claims 30 and 34 are withdrawn.

Claims 29, 31-33 are objected to as being dependent upon a rejected base claim.

***Conclusion***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

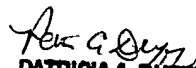


Nina A Archie

Examiner

GAU 1645

REM 3B31



PATRICIA A. DUFFY  
PRIMARY EXAMINER